DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 8, 2014

R & D Batteries, Inc.
c/o Ms. Karen Manley, Owner/Consultant
ZMT, LLC
2063 Woodbourne Terrace
Castle Rock, CO 80104

Re: K141795
Trade/Device Names: R & D Battery Pack P/N 6019
Regulatory Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: Oct. 6, 2014
Received: Oct. 23, 2014

Dear Ms. Manley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K141795

Device Name: Box, Battery, Non-Rechargeable R & D Batteries, Inc. P/N 6019

Indications for Use:

To power the functions of various devices for which batteries or battery packs are configured. Since non-rechargeable batteries and battery packs are "device specific" and are designed to operate and fit into the equipment for which they were manufactured, only qualified personnel should evaluate, test, or install these devices.

This battery is shipped only to customers who request a replacement battery for a PhysioControl LP500 AED (OEM P/N: 3005380-026, 11141-00013) or to replace a competitor's replacement battery for the same AED.

Biomedical equipment service professionals therefore know that the intended use is as a replacement battery.

Prescription Use _√___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K141795

510(k) Summary
(Per 21 CFR 807.92)

Submitter/Owner: R & D Batteries, Inc.
3300 Corporate Center Drive,
Burnsville, MN 55306 USA

Official Correspondent: ZMT, LLC
Karen Manley
Phone: 303-808-4863
Email: karen@karenmanley.com

Date Prepared: June 25, 2014

Device Name: Battery Pack, Disposable

Trade/Proprietary Name: R & D Battery Pack P/N 6019
Common/Generic Name: Box, Battery
Classification Name: Box, Battery, Non-Rechargeable
Regulatory Class III, Product Code MKJ

Predicate Devices: AMCO Battery Pack P/N 5L500

Classification:	**Cardiovascular Panel**	**Class**
21 CFR 870.5310	Automated External Defibrillator	III

510(k) Summary

R & D Batteries Replacement Battery Pack
P/N 6019

Legally Marketed Predicate Devices:

The R & D Batteries Inc. P/N 6019 is the same as the AMCO replacement battery P/N 5L500 used in the PhysioControl LP500 AED.

Device Description:

Non-rechargeable battery packs are utilized as a primary direct current (d-c) power source or as a standby or backup d-c power source for portable as well as stationary medical equipment. These devices provide a means of supplying electrical power through chemical reaction. The energy provided depends upon the voltage and capacity rating of a particular pack and the amount of current used by the device into which they are installed. The performance and life span of these batteries depends on operating conditions of temperature, current drain, and the discharge method. These parameters are taken into account in designing such batteries. The goal is to develop battery packs that maintain capacity for as high and as long as possible under a specified range of environmental conditions.

Statement of Intended Use:

To power the functions of various devices for which batteries or battery packs are configured.

Since non-rechargeable batteries and battery packs are “device specific” and are designed to operate and fit into the equipment for which they were manufactured, only qualified personnel should evaluate, test, or install these devices.

This battery is shipped only to customers who request a replacement battery for a Physio Control LP500 AED (OEM P/N: 3005380-026, 11141-00013) or to replace a competitor’s replacement battery for the same AED.

Biomedical equipment service professionals therefore know that the intended use is as a replacement battery**.**

510(k) Summary

R&D Batteries Replacement Battery Pack
P/N 6019

Substantial Equivalence:

The design components and functionality of the R & D Batteries Inc. P/N 6019 battery pack is identical to the predicate device. Cell chemistry and type are identical, Sealed (Vented) Lithium / Sulphur Dioxide (Li/SO2)

Reference: Substantial Equivalence Comparison Chart (Section 010_)

Summary of Performance and Safety Testing:

Bench tests are performed on the R & D Batteries, Inc. P/N 6019 using the applicable Medtronic's/PhysioControl LP500 AED and a NETECH Model Delta 2200 Defibrillator Analyzer including:

- Life Cycle
- Temperature
- Mechanical & Electrical Component Integrity

Reference: 013_Performance Testing for procedures and results.

Conclusions:

R&D Batteries Inc. has demonstrated through its continued evaluation and testing of the R&D Batteries Inc. P/N 6019 replacement battery pack, that this device is equivalent to the AMCO replacement battery P/N 5L500 used in the PhysioControl LP500 AED, as outlined in this submission.

The R&D Batteries Inc. P/N 6019 replacement battery pack is identical with respect to indications for use, technological characteristics, materials, form, fit, and function to those currently distributed commercially. This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission